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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,004	05/10/2007	Thomas Koehler	PHDE040056US	8994

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EXAMINER

HOFFA, ANGELA MARIE

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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08/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,004	Applicant(s) KOEHLER ET AL.	
	Examiner Angela M. Hoffa	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to communication filed on June 10, 2010.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The scope covered by the disclosure does not include that of any type of "an imaging scanner system" or "scanner adapted for acquiring an image of the heart in an imaging scan" as claimed in claims 18-20. The disclosure only describes embodiments including a computed tomography (CT) medical scanner system. Since the term "imaging scanner system" could include MRI, ultrasound, PET, and other types of imaging systems, the scope of the term is not consistent with that which is disclosed and therefore constitutes new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7, 8-9, 10, 12-14, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,397,098 to Uber.

Regarding Claim 1, Uber discloses a method of controlling a local application of drugs to a part of a body of a patient during a CT scan (col. 7, line 2), wherein the drugs are transported in containers suitable for introduction into a bloodstream of the patient (injection needle, fig. 1; molecules, col. 15, lines 1-10); wherein the containers prevent an application of the drugs (syringe/needle assembly, fig. 1; molecules are not activated to release drug initially, col. 15, lines 1-3); and wherein a first drug is transported in a first container (contrast agent, fig. 1; drug, col. 15, lines 1-2); the method comprising the steps of:

Monitoring a heart beat rate (col. 10, lines 29-31) of the patient during the CT scan (col. 7, line 2);

Rupturing the first container (injecting contrast with needle injector inserted into the blood stream; activating with x-ray to release drug, col. 15, lines 1-3) in proximity to the part of the body on the basis of the monitored heart beat rate (to increase or decrease perfusion, col. 14, lines 1-8), resulting in a local application of the first drug to the part of the body (col. 10, lines 29-31, controlled rate of contrast agent injection based on heart beat rate) and wherein the rupturing the first container results in a controlled change of the heart beat rate (activating with x-ray to release vasodilator/constrictor drugs to increase perfusion, col. 14, lines 5-8, col. 15, lines 1-3).

Regarding Claims 2 and 4, Uber further discloses wherein the drugs can be locally applied to the heart via rupturing the first container; and wherein the rupturing the first container results in a controlled change of the heart beat rate (activating with x-ray to release vasodilator/constrictor drugs to increase perfusion, col. 14, lines 5-8, col. 15, lines 1-3).

Regarding Claim 3, Uber further discloses wherein the containers can be activated via ultrasound (col. 15, lines 1-3).

Regarding Claim 7, Uber further discloses the use of microbubbles carrying drugs administered to increase and decrease cardiac output load (col. 10, lines 32-35).

The features of Claims 8-9, 10, 12-14, and 17-19 are disclosed in the rejection of claims 1-4 and 7 above.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 5-6, 15-16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uber as applied above.

Regarding Claims 5-6, 15-16, and 20, Uber further suggests that microbubbles can be selectively ruptured based on their size but does not disclose carrying two types of drugs with two differently sized microbubbles. Uber further suggests that two types of drugs are applied to vary perfusion rates of the patient for a stress test (vasodilators/vasoconstrictors) which are known to have an effect on heart beat rate (col. 14, lines 1-8). Uber further discloses the use of microbubbles carrying drugs administered to increase and decrease cardiac output load (col. 10, lines 32-35).

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to provide two differently sized microbubbles for drug delivery of vasodilators/vasoconstrictor drugs for varying heart rate during an imaged stress test as suggested by Uber.

Response to Arguments

9. No arguments were presented in the response to the previous Office Action. Although the Examiner indicated a feature in the office action mailed April 29, 2010 that would overcome the art of record, this feature is not adequately reflected in the claim language. The amended feature to the independent claims ("resulting in...a controlled change of the heart beat rate of the patient...") was previously in a dependent claim that was rejected under 102(b) and does not positively set forth any steps or structure to

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further define the method or system, respectively. Therefore, the claims remain rejected under this same statute for the reasons above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Hoffa whose telephone number is 571-270-7408. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. H./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768